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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,123	04/02/2002	Mary Collins	22058-514NATL	5639

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
02/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/868,123	COLLINS ET AL.	
	Examiner	Art Unit	
	REGINA M. DEBERRY	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,28,48-53,55,59-62 and 64-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,28,48-53,55,59-62 and 64-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 October 2007 has been entered.

Status of Application, Amendments and/or Claims

The amendment filed 29 October 2007 has been entered in full. Claims 1-22, 24-27, 29-47, 54, 56-58 and 63 are canceled. New claim 68 was added. Claims 23, 28, 48-53, 55, 59-62, 64-68 are under examination.

Withdrawn Objections And/Or Rejections

The rejection to claims 23, 28, 48, 55, 59 and 64 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-8 and 14 of U.S. Patent No. 6,248,714 B1 in view of Cookson *et al.,* US 6,387,615 B2, Hamelmann *et al.* (Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999), as set forth at pages 3-5 of the previous Office Action (07 November

2006), is *withdrawn* in view of the amendment, which establishes priority of the instant application (29 October 2007).

The rejection to claims 23, 28, 48-53, 55, 59-62, 64-67 under 35 U.S.C. 103(a) as being unpatentable over **Collins *et al.*, US Patent 5,710,023** in view of Hamelmann *et al.* (Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999), as set forth at pages 5-7 of the previous Office Action (07 November 2006), is *withdrawn* in view of the amendment, which establishes priority of the instant application (29 October 2007).

The rejection to claims 23, 28, 48-53, 55, 59-62, 64-67 under 35 U.S.C. 103(a) as being obvious over **Collins *et al.*, US Patent 6,248,714 B1** in view of Hamelmann *et al.* (Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999), as set forth at pages 7-9 of the previous Office Action (07 November 2006), is *withdrawn* in view of the amendment, which establishes priority of the instant application (29 October 2007).

The rejection to claims 23, 28, 48-53, 55, 59-62, 64-67 under 35 U.S.C. 103(a) as being obvious over **Collins *et al.*, US Patent 6,268,480 B1** in view of Hamelmann *et al.* (Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999), as set forth at pages 9-11 of the previous Office Action (07 November 2006), is

withdrawn in view of the amendment, which establishes priority of the instant application (29 October 2007).

The rejection to claims 23, 28, 48-53, 55, 59-62, 64-67 under 35 U.S.C. 103(a) as being obvious over Collins ***et al.,*** **US Patent 6,214,559 B1** in view of Hamelmann *et al.* (Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999), as set forth at pages 11-13 of the previous Office Action (07 November 2006), is *withdrawn* in view of the amendment, which establishes priority of the instant application (29 October 2007).

Matter of Record

The Examiner stated in the previous Office Action (30 July 2007) that the King et al. reference will be removed once the priority is corrected. However, Applicant was advised that all of the instant rejections can still be made and will be reapplied to the instant claims without the King et al. reference. Please see the rejections below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re*

Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23, 28, 48, 55, 59, 64 and 68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-8 and 14 of U.S. Patent No. 6,248,714 B1 in view of Cookson *et al.,* US 6,387,615 B2 (reference of record) and Hamelmann *et al.* (reference of record, Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998). The priority date is now December 14, 1998, in view of the correction to the specification. The instant references are still prior art, as was stated above in the Matter of Record.

Applicant cites case law, *Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d1322, 1326, 52 USPQ2d 1590, 1593 (Fed. Cir. 1999)* and 1327, 52 USPQ2d at 1595. Applicant states, "A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting." Applicant cites *In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998).* Applicant argues that claim 23 (of the instant application) requires inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject having an allergen-induced airway hyper responsiveness. Applicant argues that the claims of the '714 patent do not disclose inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject

having an allergen-induced airway hyper responsiveness or a method of treating an allergen-induced airway hyper responsiveness in a mammalian subject.

Applicant's arguments have been fully considered but are not deemed persuasive. Berg at page 1229 states: Obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit. It **requires** rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent. See *In re Braat* , 937 F.2d 589, 592, 19 USPQ2d 1289, 1291-92 (Fed.Cir. 1991). Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later. See *In re Goodman* , 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed.Cir. 1993). Obviousness- type double patenting is a question of law reviewed de novo by this court. See id. ; see also *General Foods v. Studiengesellschaft Kohl MbH* , 972 F.2d 1272, 1277, 23 USPQ2d 1839, 1843 (Fed.Cir. 1992).

Applicant is asked to point to particularly where Berg supports their assertion of invalidity (i.e. a later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting).

Instant claims 23, 28, 48, 55, 59, 64 and 68 are drawn to a method of inhibiting binding of IL-13 to the IL-13 receptor in a mammalian subject having an allergen-induced airway hyper responsiveness comprising administering a polypeptide comprising amino acids 26 to 341 of SEQ ID NO:4.

Claim 1 of the '714 patent is drawn to a method of inhibiting binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering SEQ ID NO:4; Claim 6 of the '714 patent is drawn to a method of treating an Ig-mediated condition in a mammalian subject comprising administering SEQ ID NO:4. Claim 7 of the '714 patent recites, "wherein said condition is an IgE-mediated condition". Claim 8 of the '714 patent recites, "wherein said condition is selected from the group consisting of an allergic condition, asthma and an immune complex disease". Water is considered a pharmaceutically acceptable carrier.

The claims of the '714 patent do not teach allergen-induced airway hyper responsiveness. Cookson et al. teach that asthma in children and young adults is initiated by IgE-mediated allergies to inhaled allergens. Hamelmann et al. teach experiments directed at treating airway hyper responsiveness (AHR) in bronchial asthma. The prior art of record teach that asthma is initiated by IgE-mediated allergies and that asthma is characterized by allergen-induced airway hyper responsiveness. The genus of treating an Ig-mediated condition, as claimed in the '741 patent, renders the species of IgE mediated condition such as allergen-induced airway hyper responsiveness, obvious. Lastly, the claims of the '714 patent broadly encompasses any mode of administration (genus) and thus renders the modes of administration (species) as recited in instant claim 68, obvious.

Claim Rejections - 35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 23, 28, 48-53, 55, 59-62, 64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Collins et al., US Patent 5,710,023** (reference of record) in view of Cookson et al., US 6,387,615 B2 (reference of record) and Hamelmann et al. (reference of record; Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998). The priority date is now December 14, 1998, in view of the correction

to the specification. The instant references are still prior art, as was stated above in the Matter of Record.

Applicant argues that the rejection under 35 USC 103(a) cannot be sustained with the remaining references. Applicant maintains that instant claims 23 and 28 are directed to the treatment of an allergen-induced airway hyper responsiveness (AHR), which is neither mentioned nor suggested in the '023 patent. Applicant submits that Hamelmann teaches away from the present invention because Hamelmann discloses that the role of cytokines in AHR is not well defined and requires further delineation. Applicant argues that Hamelmann concludes that IL-5 is a key factor in the development of airway inflammation and AHR, and suggests that anti-IL-5 therapy would be beneficial in the treatment of AHR. Applicant argues that Hamelmann does not disclose or suggest that the inhibition of IL-13 binding to IL-13 could be useful in the treatment of AHR.

Applicant's arguments have been fully considered but are not deemed persuasive. Collins et al. teach the human cDNA of IL-13 binding chain (bc) as SEQ ID NO:3 and the human polypeptide of IL-13bc as SEQ ID NO:4 (column 3, line 60-column 4, line 28). Collins et al. teach pharmaceutical compositions comprising a fusion protein. The fusion protein comprises amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 22-42 and column 3, lines 1-15). Collins et al. teach methods of inhibiting binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 39-45). Collins et al. teach the administration of IL-13bc for the

treatment of asthma (column 8, lines 1-10). Collins et al. teach IL-13bc can be administered via oral ingestion, inhalation or cutaneous, subcutaneous, or intravenous injection (column 9, lines 48-54). Collins et al. do not teach a method of treating AHR comprising administering SEQ ID NO:4.

Cookson et al. teach that asthma in children and young adults is initiated by IgE-mediated allergies to inhaled allergens. Hamelmann et al. teach experiments directed at treating AHR in bronchial asthma. Applicant's arguments that Hamelmann teaches away from the present invention is not found persuasive. The Hamelmann et al. reference does not does not criticize, discredit, or otherwise discourage administering IL-13bc (SEQ ID NO:4). Thus it is unclear how the Hamelman reference teaches away from the instant invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a method of treating asthma by administering IL-13bc as taught by Collins et al. to treat allergen-induced airway hyper responsiveness with a reasonable expectation of success. The motivation and expected success is provided by Collins et al., Cookson et al and Hamelmann et al. Collins et al. teach a mechanism for inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc. Collins et al. teach that the method can be used in the treatment of asthma. Cooke et al. teach that asthma is initiated by IgE-mediated allergies. Hamelmann et al. teach that asthma is characterized by AHR. Since asthma is characterized by AHR, it would be obvious to use the method of Collins et al. to treat AHR.

Claims 23, 28, 48-53, 55, 59-62, 64-68 are rejected under 35 U.S.C. 103(a) as being obvious over **Collins et al., US Patent 6,248,714 B1** in view of Cookson et al., US 6,387,615 B2 (reference of record) and Hamelmann et al. (reference of record; Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998). The priority date is now December 14, 1998, in view of the correction to the specification. The instant references are still prior art, as was stated above in the Matter of Record.

Collins et al. teach SEQ ID NO:3 as human cDNA of IL-13bc and SEQ ID NO:4 as the human polypeptide of IL-13 bc (column 4, lines 1-28). Collins et al. teach pharmaceutical compositions comprising a fusion protein. The fusion protein comprises amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 30-49 and column 3, lines 1-22). Collins et al. teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 45-50 and claims). Collins et al. teach the administration of IL-13bc for the treatment of asthma (column 8, lines 7-20 and claims). Collins et al. teach IL-13bc can be administered via oral ingestion, inhalation or cutaneous, subcutaneous, or intravenous injection (column 9, lines 55-61). Collins et al. do not teach a method of treating AHR comprising administering SEQ ID NO:4.

Cookson et al. teach that asthma in children and young adults is initiated by IgE-mediated allergies to inhaled allergens. Hamelmann et al. teach experiments directed at treating AHR in bronchial asthma. Applicant's arguments that Hamelmann teaches away from the present invention is not found persuasive. The Hamelmann et al.

reference does not does not criticize, discredit, or otherwise discourage administering IL-13bc (SEQ ID NO:4). Thus it is unclear how the Hamelman reference teaches away from the instant invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a method of treating asthma by administering IL-13bc (SEQ ID NO:4) as taught by Collins et al. to treat allergen-induced airway hyper responsiveness with a reasonable expectation of success. The motivation and expected success is provided by Collins et al., Cookson et al. and Hamelmann et al. Collins et al. teach a mechanism for inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc. Collins et al. teach that the method can be used in the treatment of asthma. Cooke et al. teach that asthma is initiated by IgE-mediated allergies. Hamelmann et al. teach that asthma is characterized by AHR. Since asthma is characterized by AHR, it would be obvious to use the method of Collins et al. to treat AHR.

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Collins et al. teach SEQ ID NO:3 as human cDNA of IL-13bc and SEQ ID NO:4 as the human polypeptide of IL-13bc (column 4, lines 1-30). Collins et al. teach pharmaceutical compositions comprising a fusion protein. The fusion protein comprises amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 30-65; column 3, lines 1-22 and claims). Collins et al. teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 45-50). Collins et al. teach the administration of IL-13bc for the treatment of asthma (column 8, lines 7-20). Collins et al. teach IL-13bc can be administered via oral ingestion, inhalation or cutaneous, subcutaneous, or intravenous injection (column 9, lines 55-61). Collins et al. do not teach a method of treating AHR comprising administering SEQ ID NO:4.

Cookson et al. teach that asthma in children and young adults is initiated by IgE-mediated allergies to inhaled allergens. Hamelmann et al. teach experiments directed at treating AHR in bronchial asthma. Applicant's argument that Homeland teaches away from the present invention is not found persuasive. The Hamelmann et al. reference does not does not criticize, discredit, or otherwise discourage administering IL-13bc (SEQ ID NO:4). Thus it is unclear how the Hamelmann reference teaches away from the instant invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a method of treating asthma by administering IL-13bc (SEQ ID NO:4) as taught by Collins et al. to treat allergen-induced airway hyper responsiveness with a reasonable expectation of success. The motivation and expected

success is provided by Collins et al., Cookson et al. and Hamelmann et al. Collins et al. teach a mechanism for inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc. Collins et al. teach that the method can be used in the treatment of asthma. Cooke et al. teach that asthma is initiated by IgE-mediated allergies. Hamelmann et al. teach that asthma is characterized by AHR. Since asthma is characterized by AHR, it would be obvious to use the method of Collins et al. to treat AHR.

Claims 23, 28, 48-53, 55, 59-62, 64-68 are rejected under 35 U.S.C. 103(a) as being obvious over Collins **et al., US Patent 6,214,559 B1** in view of Cookson et al., US 6,387,615 B2 (reference of record) and Hamelmann et al. (reference of record; Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998). The priority date is now December 14, 1998, in view of the correction to the specification. The instant references are still prior art, as was stated above in the Matter of Record.

Collins et al. teach SEQ ID NO:3 as the human cDNA of IL-13 binding chain of IL-13 receptor and SEQ ID NO:4 as the human protein of IL-13 binding chain of IL-13 receptor (column 4, lines 16-30). Collins et al. teach pharmaceutical compositions comprising a fusion protein, amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 30-65; column 3, lines 1-22). Collins et al. teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines

45-50). Collins et al. teach the administration of IL-13bc for the treatment of asthma (column 8, lines 7-20). Collins et al. teach IL-13bc can be administered via oral ingestion, inhalation or cutaneous, subcutaneous, or intravenous injection (column 9, lines 53-58). Collins et al. do not teach a method of treating allergen-induced airway hyper responsiveness comprising administering SEQ ID NO:4.

Cookson et al. teach that asthma in children and young adults is initiated by IgE-mediated allergies to inhaled allergens. Hamelmann et al. teach experiments directed at treating AHR in bronchial asthma. Applicant's argument that Hamelmann teaches away from the present invention is not found persuasive. The Hamelmann et al. reference does not does not criticize, discredit, or otherwise discourage administering IL-13bc (SEQ ID NO:4). Thus it is unclear how the Hamelmann reference teaches away from the instant invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a method of treating asthma by administering IL-13bc (SEQ ID NO:4) as taught by Collins et al. to treat allergen-induced airway hyper responsiveness with a reasonable expectation of success. The motivation and expected success is provided by Collins et al., Cookson et al. and Hamelmann et al. Collins et al. teach a mechanism for inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc. Collins et al. teach that the method can be used in the treatment of asthma. Cooke et al. teach that asthma is initiated by IgE-mediated allergies. Hamelmann et al. teach that asthma is characterized by AHR. Since asthma is

characterized by AHR, it would be obvious to use the method of Collins et al. to treat AHR.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINA M. DEBERRY whose telephone number is (571)272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

RMD
1/29/08